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### REMARKS

The present response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

### Status of Claims

Claims 1 - 14 are pending in the application. Claims 7 - 13 have been allowed. Claims 1 - 6 and 14 have been rejected. Claim 1 has been amended.

Applicants respectfully assert that the amendments to the claim add no new matter.

### Allowable Subject Matter

Applicants wish to thank the Examiner for allowing claims 7 - 13.

### CLAIM REJECTIONS

#### 35 U.S.C. § 112 Rejections

Claims 1 - 6 and 13 - 14 were rejected under 35 U.S.C. § 112. In particular, the Office action alleged that the limitation "zwitterion, said salt allowing simultaneous coadministration to a subject represented by", previously added to claim 1, is not supported by the original disclosure and thus, is considered as a new matter.

Without conceding the appropriateness of the rejection, applicants have amended claim 1 by removing this limitation from the claim.

Accordingly, it is requested that the 35 U.S.C. § 112 rejection be withdrawn.

#### 35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 1 - 6 and 14 under 35 U.S.C. § 103(a), as being unpatentable over Ames et al. (US 5,916,912) French Patent No. 4,512M (FR 4,512) each taken alone in view of Ekwuribe et al. (US 6,479,692).

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Applicants respectfully traverse the rejection of claims 1 - 6 and 14 under in view of the remarks that follows.

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)" [MPEE §2142]

**Ames et al in view of Erkwuribe**

Applicants respectfully submit that the Office action has not established a prima facie case of obviousness as the combination of Ames et al. and Erkwuribe does not meet the requirements of an obviousness rejection, at least in that the combination fails to teach or suggest all the claim limitations.

The Office action contends that Ames et al. discloses "salts structurally similar to the instantly claimed salts" (see page 4 of the Office action dated December 1, 2005). Applicants respectfully submit that Ames does not disclose or remotely suggest any "salt of a thioctic acid with L-carnitine", as claimed in claim 1.

Instead, Ames discloses pharmaceutical formulations comprising acetyl-L-carnitine and lipoic (thioctic) acid as two active ingredients. The active ingredients are only physically mixed (see col. 4, lines 3 - 5 and 52 - 55 of Ames). Ames et al describes "Formulation 1" as follows:

250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid are administered orally 4 x daily in 500 mg gelatin capsules (see col. 4, lines 3 - 5).

It is clear from the teaching of Ames et al. that the acetyl-L-carnitine and lipoic (thioctic) acid are two separate ingredients not chemically (ionically) bound as a salt as the formulation described above do not contains equimolar amounts of carnitine derivative and thioctic acid. A unit dosage containing a salt of carnitine and lipoic acid and having 250mg of lipoate anion would have only 195mg of L-carnitine as 250mg of lipoate anion are

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equivalent to 1.22mol of L-carnitine and 1.22mol of L-carnitine are equivalent to 195mg. Accordingly, the Ames capsule is not a salt of L-carnitine and thioctic acid.

Erkwuribe cannot cure the deficiencies of Ames et al. as Erkwuribe does not teach or suggest and the Examiner does not contend that Erkwuribe teaches or suggests "salt of a thioctic acid with L-carnitine", as claimed in claim 1.

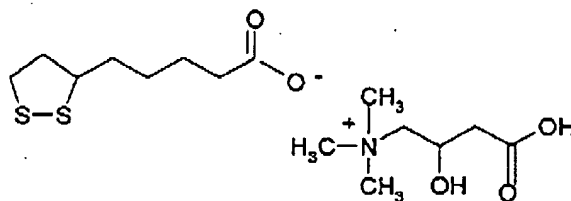
Accordingly, Applicants assert that neither the Aimes et al., nor Erkwuribe, alone or in combination, teach or suggest, at least "salt of a thioctic acid with L-carnitine" as claimed independent claim 1.

#### French Patent No. 4,512M in view of Erkwuribe

Applicants respectfully submit that the Office action has not established a prima facie case of obviousness as the combination of FR 4,512 and Ekwuribe does not meet the requirements of an obviousness rejection, at least in that the combination fails to teach or suggest all the claim limitations or alternatively fails to show a reasonable expectation of success.

The Office action contends that French Patent 4,512M discloses "salts structurally similar to the instantly claimed salts" (see page 4 of the Office action dated December 1, 2005). Applicants respectfully submit that FR 4,512 does not disclose "salt of a thioctic acid with L-carnitine", as claimed in claim 1.

FR 4,512 presents a salt between L-carnitine and thiooctic acid having the formula illustrated below but fails to disclose the process for making such a salt.



Section 2121.02 of the MPEP recites:

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**ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO  
MAKE OR SYNTHESIZE**

Where a process for making the compound is not developed until after the date of invention, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound. *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968)

Applicant provides evidence showing that a process for making the salt disclosed by the FR 4,512 reference was not known at the time of the invention in the form of an expert declaration from Mr. Nardi Antonio attached herewith. This declaration describes various experimental attempts carried out under Mr. Nardi Antonio's responsibility, which were previously disclosed in the specification of the subject application, to prepare the salt disclosed by the FR 4,512 reference using several different reactions parameters and conditions. None of these attempts were successful.

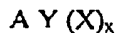
Accordingly, a person skilled in the art would not be able from the teaching of the FR 4,512 reference to prepare salt of a thioctic acid with L-carnitine. Therefore, Applicants respectfully submits that FR 4,512 does not disclose a "salt of a thioctic acid with L-carnitine", as claimed in claim 1.

Moreover, the office action dated December 1, 2005 contends that Ekwuribe et al. discloses that "salts such as alkaline metal salts, alkaline earth metal salts are salts that retain the desired biological activity of the parent compounds" and that "there is ample motivation for one of ordinary skill in the art to modify the [FR 4,512] compounds to arrive at the instantly claimed salts".

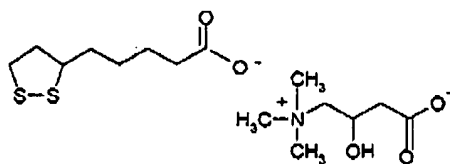
Without conceding the appropriateness of the combination, Applicants respectfully submit that even if a person skilled in the art, from the teaching of the FR 4,512 reference, would believe that the salt illustrated in the reference can be prepared, he would not be motivated to prepare an alkaline metal salt or alkaline earth metal salt of an L-carnitine with a thioctic acid from the salt between L-carnitine and thioctic acid and indeed such a reaction is impossible. The person skilled in the art would realize that the alkaline metal would break the ionic bond between the L-carnitine and thioctic acid and accordingly there is no reasonable expectation of success in the FR 4,512 reference.

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Accordingly, Applicants assert that neither the FR 4,512 reference, nor Erkwuribe, alone or in combination, teach or suggest, at least "salt of a thioctic acid with L-carnitine represented by the formula:



where A is



where Y is the cation of an alkaline metal, of an alkaline earth metal or is a quaternary ammonium group,

X is A or OH<sup>-</sup>,

x is equal to 0 when Y is the cation of an alkaline metal or a quaternary ammonium group and equal to 1 when Y is an alkaline earth metal" as claimed independent claim 1.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Accordingly, Applicants respectfully assert that claim 1 is allowable. Claims 2 - 6 and 14 depend from, directly or indirectly, claim 1, and therefore include all the limitations of claim 1. Therefore, Applicants respectfully assert that claims 2 - 6 and 14 are likewise allowable. Accordingly, Applicants respectfully request that the prior art rejections of claims 2-6 and 14 be withdrawn.

### CONCLUSION

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

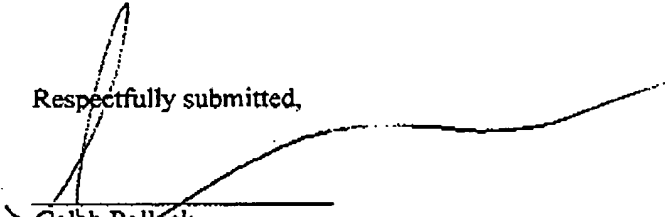
Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the

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prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

The fees for the petition for extension of time and RCE are being paid separately. No other fees are believed to be due. However, if any such fees are due, please charge such fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: January 2, 2007

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